

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	) ) ) ) _____	MDL NO. 1203
THIS DOCUMENT RELATES TO:	) )	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	) )	2:16 MD 1203

**MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.**

Bartle, J.

August 21, 2012

Sandra Wollschlager ("Ms. Wollschlager" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,<sup>1</sup> seeks benefits from the AHP Settlement Trust ("Trust").<sup>2</sup> Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").<sup>3</sup>

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Robert B. Wollschlager, Ms. Wollschlager's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the

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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is to be completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In April 2003, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Azam Ansari, M.D., F.A.C.C. Dr. Ansari is no stranger to this litigation. According to the Trust, he has signed in excess of 163 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated April 4, 2003, Dr. Ansari attested in Part II of Ms. Wollschlager's Green Form that she suffered from moderate mitral regurgitation, an abnormal left atrial dimension,

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3. (...continued)

presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. and IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

and an ejection fraction in the range of 50% to 60%.<sup>4</sup> Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$545,310.<sup>5</sup>

In the report of claimant's echocardiogram, Dr. Ansari found that claimant suffered from "moderate mitral regurgitation, which occupied 28% of the left atrial surface area." Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In October 2003, the Trust forwarded the claim for review by Stephen G. Sawada, M.D., one of its auditing cardiologists. In audit, Dr. Sawada concluded that there was no reasonable medical basis for Dr. Ansari's finding of moderate mitral regurgitation because claimant only had physiologic mitral regurgitation.<sup>6</sup> In support of this conclusion, Dr. Sawada

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4. Dr. Ansari also attested that claimant had moderate aortic regurgitation. This condition is not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's finding of an abnormal left atrial dimension, which is one of the conditions needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

6. Physiologic regurgitation is defined as a "[n]on-sustained  
(continued...)

explained that the "original [echocardiogram] measurement of jet area included mostly displaced blood rather than regurgitant jet."

Based on the auditing cardiologist's finding that claimant had physiologic mitral regurgitation, the Trust issued a post-audit determination denying Ms. Wollschlager's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.<sup>7</sup> In contest, claimant submitted a supplemental report by Dr. Ansari, who reaffirmed his finding of moderate mitral regurgitation and attached several still frames from the echocardiogram, which purportedly demonstrated moderate mitral regurgitation. Claimant also argued that: (1) the attesting physician relied upon a computerized visual assessment of her echocardiogram, which measured her mitral regurgitation to be greater than 20%; and (2) the audit process is flawed because

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6. (...continued)  
jet immediately (within 1 cm) behind the annular plane or  $\leq + 5\%$  RJA/LAA." See Report of Auditing Cardiologist Opinions Concerning Green Form Questions at Issue, at 2.

7. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Wollschlager's claim.

there are additional answer choices on the Report of the Auditing Cardiologist that do not appear on the Green Form.<sup>8</sup>

The Trust then issued a final post-audit determination, again denying Ms. Wollschlager's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Wollschlager's claim should be paid. On November 17, 2004, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 4142 (Nov. 17, 2004).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on June 14, 2005, and claimant submitted a sur-reply on July 27, 2005. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor<sup>9</sup> to review claims after the Trust and claimant

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8. Claimant also contended that the auditing cardiologist should be required to declare under penalty of perjury that the information contained in the Report of the Auditing Cardiologist is correct to the best of his or her knowledge. In making this assertion, however, claimant ignores that Dr. Sawada signed an Attestation Form dated January 5, 2004 and a Certification dated June 16, 2004 averring that his findings were true and correct. See generally Audit Rule 7.

9. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon (continued...)

have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, James F. Burke, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other had, we conclude that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Wollschlager asserts that the auditing cardiologist "eyeballed" her level of mitral regurgitation, which, according to claimant, is an unacceptable

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9. (...continued)

and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

method of measurement. She further alleges that the Report of Auditing Cardiologist contains additional answer choices that are not present on the Green Form.<sup>10</sup> Claimant also maintains that the auditing cardiologist "selectively downgraded" her level of mitral regurgitation and that the auditing cardiologist's findings lack verifiable evidence. Finally, claimant argues that the auditing cardiologist is "indecisive" because he stated she had both physiologic mitral regurgitation and no mitral regurgitation and that there is no reason for the auditing cardiologist to have found she had only physiologic mitral regurgitation.

In response, the Trust disputes claimant's contention that the auditing cardiologist selectively downgraded claimant's level of mitral regurgitation. Instead, the Trust explains that the auditing cardiologist concluded that, because the attesting physician included backflow as mitral regurgitation, there was no reasonable medical basis to find moderate mitral regurgitation. The Trust further argues that eyeballing an echocardiogram is an accepted methodology. Finally, the Trust contends that the additional possible responses included in the Report of Auditing Cardiologist have no effect on the outcome of claims, and that

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10. Claimant also submitted a new verified expert opinion from Dr. Ansari and several color still frames. Claimant, however, failed to make the requisite showing of good cause for the submission of this new evidence. See Audit Rule 26. Moreover, claimant's contest materials already contained an expert report and color still frames. Accordingly, the Special Master denied claimant's request to submit new evidence by letter on April 8, 2005.



claimant's broad-based criticisms of the Trust's administration of claims is beyond the scope of the show cause proceedings.

In her sur-reply, claimant avers that the Green Form definition of mitral regurgitation provides that "[mitral regurgitation] was considered to be present if blue, green, or mosaic signals were seen originating from the mitral valve and spreading into the left atrium during systole." Claimant argues that, as this definition does not mention "low velocity, background noise, backflow, [or] displaced blood...", the auditing cardiologist improperly considered these characteristics in describing the tracings made by her attesting physician. Claimant further maintains that her attesting physician used "computerized measurement[s] and visual assessment," which demonstrated moderate mitral regurgitation, while the auditing cardiologist failed to produce "any independently verifiable evidence" in support of his finding of physiologic mitral regurgitation.

The Technical Advisor, Dr. Burke, reviewed claimant's April 4, 2002 echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation. Dr. Burke calculated the RJA/LAA ratio to be less than 4.2% in each relevant view, and determined that claimant's RJA was overestimated by the attesting physician. Specifically, Dr. Burke stated that:



The mitral regurgitant jet area traced by the attesting physician included low velocity color Doppler signals that were clearly not part of the mitral regurgitation. These signals may be caused by pulmonary vein flow, backflow, entrainment, or eddy currents. It was not appropriate to include these signals in the tracing of the mitral regurgitant jet.

In response to the Technical Advisor Report, claimant argues that Dr. Burke ignores the Green Form criteria by improperly excluding backflow when, according to claimant, backflow is mitral regurgitation and "signifies the dysfunction of the mitral valve."<sup>11</sup>

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, we disagree with claimant that the auditing cardiologist's finding lacks verifiable evidence and that Dr. Burke did not substantiate his findings. To the contrary, the auditing cardiologist identified specific deficiencies with Dr. Ansari's measurements, namely, that he included "mostly displaced blood rather than regurgitant jet."<sup>12</sup> Dr. Burke also noted that Dr. Ansari included low velocity that was not part of the regurgitant jet. On these bases alone, claimant has failed to meet her burden of

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11. Claimant also contends that Dr. Burke lacks the necessary credentials to be a Technical Advisor as set forth in Audit Rule 32. We disagree. We appointed Dr. Burke to assist the court in reviewing certain claims in the show cause process after finding that he possessed the requisite skills and expertise. See PTO No. 3212 (Jan. 14, 2002).

12. The auditing cardiologist, therefore, did not selectively downgrade claimant's level of mitral regurgitation from moderate to physiologic.

demonstrating that there is a reasonable medical basis for her claim.<sup>13</sup>

We also disagree with claimant that "backflow" is considered mitral regurgitation. As we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See PTO No. 2640 at 9-13, 15, 21-22, 26 (Nov. 14, 2002). Here, Dr. Sawada and Dr. Burke both found that claimant's attesting physician improperly relied on measurements containing "backflow." Such reliance by claimant's attesting physician cannot provide a reasonable medical basis for the resulting diagnosis and Green Form answer of moderate mitral regurgitation.

Moreover, claimant's arguments concerning the required method for evaluating a claimant's level of valvular regurgitation are without merit. Although the Settlement

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13. For these reasons as well, the still frames submitted by claimant are insufficient to establish a reasonable medical basis for her claim.

Agreement specifies the percentage of regurgitation needed to qualify as having moderate mitral regurgitation, it does not specify that actual measurements must be made on an echocardiogram. As we explained in PTO No. 2640, "'[e]yeballing' the regurgitant jet to assess severity is well accepted in the world of cardiology." See id. at 15. Claimant essentially requests that we write into the Settlement Agreement a requirement that actual measurements of mitral regurgitation be made to determine if a claimant qualifies for Matrix Benefits. There is no basis for such a revision, and claimant's contention is contrary to the "eyeballing" standards we previously have evaluated and accepted in PTO No. 2640.<sup>14</sup>

Finally, we are not persuaded by claimant's assertion that the Trust's audit system is unfair to claimants. It is claimant's burden in the show cause process to show why she is entitled to Matrix Benefits. See Audit Rule 24. The audit and show cause process, as approved by this court, provide claimant with notice and an opportunity to present her evidence in support of her claim.<sup>15</sup> Claimant has not provided any evidence that the

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14. In any event, Dr. Burke measured claimant's RJA/LAA ratio as less than 4%.

15. We also reject claimant's argument that there are inconsistencies between the possible answers on the Green Form and the Auditor's Report. Although the Auditor's Report includes additional selections for the level of mitral regurgitation, these choices have no bearing on whether a claimant is eligible for Matrix Benefits.

audit of her claim was not done in an objective manner. We, therefore, reject claimant's challenge to the audit process.

For the foregoing reasons, we conclude that claimant has not met her burden in proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Wollschlager's claim for Matrix Benefits and the related derivative claim submitted by her spouse.